

REMARKS

Claims 1-33 are pending and are rejected. Each of the dependent claims (claims 1, 10, 18, 24, 28, 29, and 32) is amended. Applicant respectfully requests reconsideration for the following reasons, and appreciates the Examiner's agreement to an interview prior to the next action, pursuant to a January 20, 2004 telephone conversation with the undersigned representative.

REJECTIONS UNDER 35 U.S.C. §102

Claims 1-10, 13-29, and 31-33 are rejected under 35 U.S.C. §102(b) as anticipated by Boyce, *Med. Biol. Eng. Comput.* 36:791-800, 1998 (hereinafter referred to as "the Boyce 1998 publication"). Applicant respectfully disagrees.

The Examiner finds, with respect to all the independent claims except claim 32, that the Boyce 1998 publication "teaches a cultured skin substitute comprising cultured dermal cells on Collagen-GAG matrix, which further provides a lamination layer for cultured keratinocytes." (Office Action page 2, last paragraph, emphasis in original).

Applicant respectfully disagrees. No portion of the Boyce 1998 publication is cited in support of this statement, and applicant respectfully asserts that none can be cited because it does not contain this teaching. The Boyce 1998 publication does not teach a cellular lamination layer and thus does not anticipate the claimed invention. As further described below, the claimed cultured skin device contains a cellular lamination layer. All of the claims recite this feature, or have been amended to clarify this feature.

Applicant respectfully asserts that the Boyce 1998 publication does not enable the full scope of the claimed invention, as required for a reference to anticipate

the claimed invention (e.g., M.P.E.P. §2121).

With respect to the claimed device, the Boyce 1998 publication contains no enabling disclosure for a matrix having a cellular lamination layer. This is because the Boyce 1998 publication does not disclose a lamination layer on a matrix at all, so that it cannot disclose a cellular lamination layer.

With respect to the claimed methods of producing the device or inoculating the matrix, the Boyce 1998 publication does not disclose any methods for producing a cultured skin substitute. The list of materials in Table 1 (page 792) does not enable one skilled in the art to produce a cultured skin substitute, at least because there is no teaching of relative placement of components to form a cellular lamination layer. The abstract (second sentence, page 791) discloses only that cells (keratinocytes and fibroblasts) are "attached to" the substrate; again, there is no disclosure of how to provide these relative to one another to form a cellular lamination layer.

With respect to independent claim 32, the Office Action did not apply the 1998 Boyce publication.

For at least these reasons, applicant believes that the rejections under §102(b) are overcome, and requests that they be withdrawn.

REJECTIONS UNDER 35 U.S.C. §103

Claims 11-12, and 30 are rejected under 35 U.S.C. §103(a) as obvious over the 1998 Boyce publication (cited previously), further in view of U.S. Patent No. 5,976,878.

Claims 11-12 depend from claim independent 10, and claim 30 depends from independent claim 29. For the reasons previously analyzed, the Boyce 1998 publication is not applicable to these independent claims. Therefore, applicant respectfully asserts that the Boyce 1998 publication in view of the '878 patent does not render dependent claims 11-12 and 30 obvious.

For at least these reasons, applicant believes that the rejections under §103(a) are overcome, and requests that they be withdrawn.

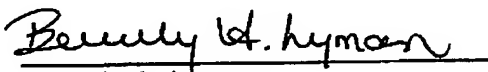
CONCLUSION

For the foregoing reasons, applicant's invention is believed to be patentable and an early Notice of Allowance is respectfully requested.

Applicant does not believe any fee is due with this submission. However, the Examiner is authorized to charge any fee deficiency to Deposit Account Number 23-3000. The Examiner is invited to telephone the undersigned attorney if there are any questions.

Respectfully submitted,

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